

### AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all previous listings of claims in this application. Please withdraw claims 22–24, 31–34, and 41–44 from consideration. Please amend claims 1–21 and 35–40 as follows:

1. (Currently amended) In a pneumatically controlled continuous positive airway pressure apparatus for supplying breathable gas from a pressurized source to an individual's breathing appliance, which appliance has an inlet for receiving the gas and an inhalation/exhalation valve for routing the gas to the individual's lungs and the exhaled air to the atmosphere, the apparatus comprising:

a demand valve assembly having a supply inlet port adapted to be fluidly connected to the pressurized source, an outlet port adapted to be fluidly connected to the appliance's inlet, a reference chamber and a control ~~valve~~ assembly responsive to a pressure differential between a [[the]] reference chamber pressure and ~~a pressure representative of the appliance inlet pressure~~ an outlet port pressure for fluidly connecting and disconnecting the inlet port to and from the outlet port; and

at least one adjustable back pressure regulator fluidly connected to the pressurized source and the reference chamber for setting the pressure in the reference chamber at a selected level above atmospheric pressure.

2. (Currently amended) ~~The invention of claim 1~~ apparatus of claim 1, wherein the demand valve assembly includes an outlet chamber upstream from the outlet port, the pressure in the outlet chamber being representative of ~~the~~ a pressure in ~~the~~ a breathing appliance inlet fluidly connected therewith.

3. (Currently amended) ~~The invention of claim 1~~ apparatus of claim 1, wherein the demand valve assembly includes a ~~first or~~ main valve ~~connected~~ disposed between the inlet and outlet ports and ~~a main valve controller responsive to the difference in the pressure in the reference chamber and the representative appliance inlet pressure for causing,~~ wherein the control assembly causes the ~~first~~ main valve to open and fluidly connect the inlet port to the outlet port when the ~~representative appliance inlet~~ outlet port pressure falls below the pressure in the reference chamber and for causing the main valve to close to fluidly disconnect the inlet from the

outlet port when ~~the representative of the breathing appliance inlet~~ outlet port pressure rises to the pressure in the reference chamber.

4. (Currently amended) The ~~invention of claim 3~~ apparatus of claim 3, wherein the ~~main valve controller~~ control assembly comprises a ~~second~~ control valve.

5. (Currently amended) The ~~invention of claim 4~~ apparatus of claim 4, wherein the demand valve assembly includes a pressurized nebulizer outlet and a ~~third~~ nebulizer valve responsive to the status of the ~~second~~ control valve for fluidly connecting and disconnecting the nebulizer outlet to the inlet port when the ~~second~~ control valve is closed and opened, respectively.

6. (Currently amended) The ~~invention of claim 4~~ apparatus of claim 4, wherein the main valve comprises a diaphragm valve with first and second actuating chambers disposed on opposite sides of the diaphragm, the area of the diaphragm exposed to the second chamber being smaller than the area of the diaphragm exposed to the first chamber whereby the main valve will remain closed when the pressure in the two actuating chambers is substantially the same and will open when the pressure in the first chamber falls below the pressure in the second chamber by a preset amount.

7. (Currently amended) The ~~invention of claim 6~~ apparatus of claim 5, wherein the ~~third~~ nebulizer valve is a diaphragm valve with first and second chambers disposed on opposite sides of the diaphragm, the first chamber being in fluid communication with the first chamber of the main valve, the second chamber of the ~~third~~ nebulizer valve being in fluid communication with the nebulizer outlet and with the second chamber of the main valve through a flow restrictor.

8. (Currently amended) The ~~invention of claim 6~~ apparatus of claim 6, wherein the ~~second~~ control valve comprises a diaphragm valve with the reference chamber and a second chamber disposed on opposite sides of a pressure sensing diaphragm, the second chamber being in fluid communication with the outlet port.

9. (Currently amended) The ~~invention of claim 8~~ apparatus of claim 8, wherein both chambers of the main diaphragm valve are fluidly connected to the inlet port, the fluid connection to the first chamber including a restrictor for restricting the flow rate.

10. (Currently amended) The ~~invention of claim 9~~ apparatus of claim 9, wherein the ~~second diaphragm valve control assembly~~ further includes a normally closed pilot valve fluidly connected to the first chamber of the main valve, the pilot valve opening to fluidly connect the first chamber of the main valve to the second chamber of the ~~second control~~ valve in response to the movement of the sensing diaphragm as a result of the pressure in the second chamber of the ~~second control~~ valve falling below the pressure in the reference chamber.

11. (Currently amended) The ~~invention of claim 10~~ apparatus of claim 10, wherein the pilot valve includes a spring biased member which maintains the pilot valve normally closed.

12. (Currently amended) The ~~invention~~ apparatus of claim 9, further comprising a nebulizer valve, wherein the ~~third nebulizer~~ valve is a diaphragm valve having first and second actuating chambers disposed on opposite sides of the diaphragm, the first chamber being in fluid communication with the first chamber of the main valve, the second chamber being in fluid communication with ~~[[the]]~~ a pressurized nebulizer outlet.

13. (Currently amended) The ~~invention of claim 3~~ apparatus of claim 3, wherein ~~said~~ at least one adjustable pressure regulator includes a line with a flow restrictor fluidly connected between the pressurized source and the reference chamber and a first adjustable poppet valve fluidly connected between said line upstream from the flow restrictor and atmosphere.

14. (Currently amended) The ~~invention of claim 4~~ apparatus of claim 4, wherein said at least one pressure regulator comprises two pressure regulators, at least one which is manually adjustable and a inhalation/exhalation selector, the two pressure regulators in conjunction with the selector being arranged to set the pressure in the reference chamber at one level during the inhalation phase and at a different level during the exhalation phase.

15. (Currently amended) The ~~invention of claim 14~~ apparatus of claim 14, wherein the reference chamber is fluidly connected to the pressurized source through a restrictor and wherein each pressure regulator includes a poppet valve, each poppet valve having an inlet and an outlet, the outlets being in fluid communication with the atmosphere, the inlet of one of the poppet valves being in constant fluid communication with the reference chamber upstream from the restrictor, and further including a ~~fourth~~ selector valve for placing the inlet of the other

poppet valve in fluid communication with the reference chamber, upstream of the restrictor, in response to the closure of the main valve.

16. (Currently amended) The ~~invention of claim 15~~ apparatus of claim 15, wherein both pressure regulators are manually adjustable.

17. (Currently amended) The ~~invention of claim 15~~ apparatus of claim 15, wherein the ~~fourth~~ selector valve is a diaphragm valve.

18. (Currently amended) The ~~invention of claim 17~~ apparatus of claim 17, wherein the ~~fourth~~ selector valve includes first and second chambers disposed on opposite sides of the diaphragm with the first chamber being in fluid communication with ~~[[the]]~~ a nebulizer outlet and the second chamber being in fluid communication with the reference chamber.

19. (Currently amended) The ~~invention of claim 14~~ apparatus of claim 14, wherein the other pressure regulator is not manually adjustable by an operator in the field and functions to set the pressure in the reference chamber at a set pressure above the exhalation reference pressure during the inhalation phase.

20. (Currently amended) The ~~invention of claim 19~~ apparatus of claim 19, wherein each of the pressure regulators includes a poppet valve and the selector comprises a diaphragm valve.

21. (Currently amended) The ~~invention of claim 2~~ apparatus of claim 2, further including a nozzle disposed upstream of the outlet port and in an educting relationship with the outlet chamber so that the pressure in the outlet chamber varies with the flow rate of gas through the nozzle to compensate for pressure losses between the outlet port and the breathing appliance inlet.

22. (Withdrawn) A method of treating a patient suffering from pulmonary edema or other respiratory ailments comprising:

a) securing a breathing appliance to the patient's airway, the appliance having an inlet and an inhalation/exhalation valve to allow breathable gas passing through the inlet to enter the patient's lungs during the inhalation phase and allow expired air to exit to atmosphere during the exhalation phase;

b) providing a pressurized source of breathable gas;

c) providing at least one reference pressure at a selected value above atmospheric pressure;

d) monitoring the pressure at the appliance inlet;

e) comparing the appliance inlet pressure with the reference pressure;

f) connecting and disconnecting the pressurized source to the mask inlet when the inlet pressure falls below and rises to the reference pressure, respectively; and

g) varying the selected value of the reference pressure during the treatment.

23. (Withdrawn) The method of claim 22 wherein the reference pressure is varied to accommodate the patient's ability to tolerate higher or lower lung pressures.

24. (Withdrawn) The method of claim 23 wherein the reference pressure is varied so that the reference pressure is greater during inhalation than during exhalation.

25-30 (Canceled)

31. (Withdrawn) A patient inhalation/exhalation valve for directing breathable gas from a pressure regulated source to a patient's lungs and exhausting the patient's expired air to the atmosphere comprising:

a housing having an upper section and an interior wall, the housing further having an inlet adapted to be connected to the regulated source, an exhaust port in fluid with the atmosphere and an inlet/outlet chamber adapted to be placed in fluid communication with the patient's lungs;

an inhalation valve disposed between the inlet and the inlet/outlet chamber;

a flexible diaphragm secured at its periphery to the inner wall of the housing and suspending a rigid valve member, the diaphragm and valve member forming a first chamber with the interior of the upper housing section;

the inlet/outlet chamber terminating at its upper end in a circular valve seat arranged to engage a lower circular sealing area of the rigid valve member, the valve member and the seat forming an exhalation valve so that when the valve member is positioned above the seat the exhalation valve is opened connecting the inlet/outlet chamber to the exhaust port and when the valve member engages the seat the exhalation valve is closed;

the first chamber being in fluid communication with the housing inlet;

the effective area of the diaphragm and valve member supported thereby being about equal to the area of the circular valve seat whereby the exhalation pressure is maintained at a level approximately equal to the pressure in the inlet.

32. (Withdrawn) The invention of claim 31 wherein the housing defines an annular exhalation chamber surrounding the valve seat in fluid communication with the exhaust port.

33. (Withdrawn) The invention of claim 32 wherein the exhaust port is formed in an exhaust casing rotatably mounted on the housing.

34. (Withdrawn) The invention of claim 33 wherein the diameter  $d_1$  of the effective area of the diaphragm and the medium diameter  $d_2$  valve member seat is substantially equal.

35. (Currently amended) In a pneumatically controlled CPAP apparatus for supplying breathable  $O_2$  from a pressurized source to an individual's breathing appliance, which appliance has a patient valve with an inlet for receiving the  $O_2$  and an inhalation/exhalation valve for routing the  $O_2$  to the individual's lungs and the exhaled air to the atmosphere, the apparatus comprising:

a demand valve having a supply inlet port adapted to be connected to the pressurized source, an outlet port adapted to be connected to the appliance's inlet and a valve assembly responsive to a reference pressure and an appliance inlet pressure for connecting the inlet port to the outlet port when the appliance inlet pressure falls below the reference pressure and for disconnecting the inlet port from the outlet port when the appliance inlet pressure rises to the reference pressure; and

at least one adjustable back pressure regulator coupled to the demand valve for allowing an operator to set the reference pressure at a selected level above atmospheric and change that level during the treatment of a patient.

36. (Currently amended) ~~The invention of claim 35~~ apparatus of claim 35, wherein said at least one pressure regulator comprises two pressure regulators, one of which is manually adjustable by the operator and an inhalation/exhalation selector, the two pressure regulators in conjunction with the selector being arranged to set the reference pressure at one level during the inhalation phase and at a lower level during the exhalation phase.

37. (Currently amended) ~~The invention of claim 35~~ apparatus of claim 35, wherein the demand valve includes a pressurized nebulizer outlet and a valve responsive to the

flow of O<sub>2</sub> between the inlet and outlet port for connecting and disconnecting the nebulizer outlet to the inlet port when the inlet port is connected to and disconnected from the outlet port, respectively.

38. (Currently amended) The ~~invention of claim 35~~ apparatus of claim 35, further including a pressure gauge connected to the demand valve to inform an operator of the selected reference pressure.

39. (Currently amended) The ~~invention of claim 38~~ apparatus of claim 38, wherein said at least one operator adjustable pressure regulator is connected to the pressurized source as well as to the demand valve and wherein the demand valve includes a reference chamber for receiving the reference pressure and wherein the valve assembly is arranged to compare the appliance inlet pressure with the pressure in the reference chamber.

40. (Currently amended) The ~~invention of claim 39~~ apparatus of claim 39, wherein said at least one operator adjustable pressure regulator includes a line with a flow restrictor connected between the pressurized source and the reference chamber and a first adjustable poppet valve connected between said line upstream from the flow restrictor and atmosphere.

41. (Withdrawn) A CPAP apparatus comprising:

a source of pressurized O<sub>2</sub>;

a balanced inhalation/exhalation valve having an inlet for receiving O<sub>2</sub>, and inlet/outlet chamber adapted to be placed in fluid communication with a patient's lungs and a discharge outlet to atmosphere, the inhalation/exhalation valve allowing a patient to inhale O<sub>2</sub> passing through the inlet and exhale gas through the discharge outlet, the inhalation/exhalation valve including a balanced diaphragm valve separating the inlet/outlet chamber from the discharge outlet to maintain the exhalation pressure at a level substantially equal to the inhalation pressure;

a demand valve having a supply inlet port connected to the O<sub>2</sub> source, an outlet port connected to the inhalation/exhalation valve inlet and a valve assembly responsive to a reference pressure and the inhalation/exhalation valve inlet pressure for connecting the inlet port to the outlet port when the inhalation/exhalation inlet pressure falls below the

reference pressure and for disconnecting the inlet port from the outlet port when the inhalation/exhalation inlet pressure rises to the reference pressure; and

at least one manually adjustable pressure regulator connected to the demand valve for allowing an operator to set the reference pressure at a selected level above atmospheric before and/or during the treatment of a patient.

42. (Withdrawn) The invention of claim 41 further including a pressure gauge connected to the demand valve to inform the operator of the reference pressure.

43. (Withdrawn) The invention of claim 42 wherein the balanced diaphragm valve separating the inlet/outlet chamber of the inhalation/exhalation valve has substantially equal areas exposed to the pressure exiting the inlet/outlet chamber and to the atmosphere pressure.

44. (Withdrawn) The invention of claim 43 wherein the pressure regulator is connected to the pressurized source as well as the demand valve and wherein the demand valve includes a reference chamber which receives the selected reference pressure from the pressure regulator.



Appl. No. : 10/020,544  
Amendment dated July 19, 2004  
Responsive to an Office Action mailed on March 23, 2004

## SUMMARY OF INTERVIEW

### Identification of Claims Discussed

Claims 1–21 and 35–44.

### Identification of Prior Art Discussed

Hatch (U.S. Patent No. 4,838,257).

### Proposed Amendments

Propose amending claims to recite “a *pneumatically controlled* continuous positive airway pressure apparatus”

### Principal Arguments and Other Matters

Hatch discloses a computer controlled CPAP apparatus.

### Results of Interview

The Examiner agreed that Hatch discloses a computer controlled device, not a pneumatically controlled device. The Examiner agreed that with respect to the 35 U.S.C. § 103 rejections, the computer controlled Hatch device could not be combined with secondary references disclosing pneumatically controlled devices. An updated search will be performed by the Examiner after submission of an amendment.